K060744

Abbreviated 510(k) Summary
March 17, 2006

JUN - 2 2006

Device Type:	Sleep Apnea/Anti-Snoring Device
Applicant:	O'Brien Dental Lab, Inc.
Contact person:	Suzie Downing Executive Assistant 541-754-1238 (office) 541-754-7478 (fax) suzie@obrien-dl.com
MD#:	6025024-956733
Trade Name:	O'Brien MPA
Common Name:	Oral Appliance / Anti-Snoring Device
Classification Name:	Anti-Snoring Device
Classification Reg.:	Class II (special controls)
Panel:	Dental
Product Code:	LRK
Predicate Devices:	SUAD – K023836 TAP – K962516 OASYS – Oral Airway System – K030440

Description: The O'Brien MPA is made of thermal plastic material (ADA approved materials). It is a very simple device that fits snugly over the upper and lower anterior teeth in such a way as to keep the mandible in a stationary, anterior protrusive position. The reason for this is to physically open the airway and thus potentially reduce the occurrence of snoring and sleep apnea. (This theory of airway management is common, standard operating procedures in the emergency medical field for airway management purposes.) The device also includes air channels to allow breathing through the mouth.

Intended Use: The O'Brien MPA is intended to reduce snoring and to treat mild to moderate obstructive sleep apnea. This individually fabricated, non-sterile prescription device is a single patient, multi-use product for use at home or in a sleep laboratory.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 2 2006

Ms. Suzie Downing
Executive Assistant
O' Brien Dental Lab, Incorporated
4311 SW Research Way
Corvallis, Oregon 97333

Re: K060744
Trade/Device Name: O'Brien MPA (Mandibular Positioning Appliance)
Regulation Number: 872.5570
Regulation Name: Intraoral Devices for Snoring Intraoral Devices for Snoring and Obstructive Sleep Apnea
Regulatory Class: II
Product Code: LRK
Dated: May 19, 2006
Received: May 23, 2006

Dear Ms. Downing:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

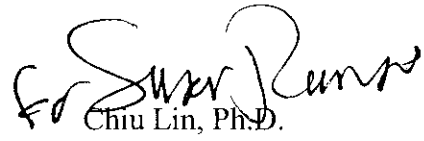
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K060744

Indications for Use

510(k) Number (if known): K060744

Device Name: O'Brien MPA (Mandibular Positioning Appliance)

Indications For Use: The O'Brien MPA is intended to reduce snoring and to treat mild to moderate OSA (obstructive sleep apnea). This individually fabricated, non-sterile, prescription device is a single patient, multi-use product for use at home or in a sleep laboratory.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Susan Runyer

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices
(Division Sign-Off) Number: K060744